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Re-evaluation Decision RVD2018-31

Cydia pomonella granulovirus (strain CMGv4) and Its Associated End-use Product

Final Decision

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Cydia pomonella granulovirus (CpGV) strain CMGv4 is a naturally occurring baculovirus that is used as a microbial pest control agent for the control of codling moth on apple trees. The commercial end-use product is formulated as a suspension and is applied as a spray to the fruit and leaves of apple trees using ground application equipment. Currently registered products containing CpGV strain CMGv4 are listed in Appendix I.

This document presents the final regulatory decision[1] for the re-evaluation of CpGV strain CMGv4 including the required updated risk mitigation measures to protect human health and the environment. All pest control products containing CpGV strain CMGv4 that are registered in Canada are subject to this re-evaluation decision. Prior to finalizing this decision, Health Canada published the Proposed Re-evaluation Decision PRVD2018-11, *Cydia pomonella* granulovirus (strain CMGv4) *and Its Associated End-use Products*, for 90-day consultation.[2]

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2018-11.

A reference list of all data used as the basis for the re-evaluation decision is included in PRVD2018-11.

Regulatory Decision for *Cydia pomonella* granulovirus strain CMGv4

Health Canada has completed the re-evaluation for CpGV strain CMGv4. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing CpGV strain CMGv4 is acceptable. Following a scientific review of the available information, Health Canada has determined that the health and environmental risks and the value of CpGV strain CMGv4 continue to be acceptable provided that the required label amendments are implemented. Label amendments, as summarized below and listed in Appendix II, are required. No additional data are requested at this time.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Risk Mitigation Measures

Registered pesticide product labels include specific instructions for use. Directions must be followed by law and include risk mitigation measures to protect human health and the environment. The following label amendments are included as part of the re-evaluation:

- Personal protective equipment label statement;
- Environmental hazard label statements;
- Restricted-entry interval label statement.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing CpGV strain CMGv4 that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on CpGV strain CMGv4 within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered *Cydia pomonella* granulovirus strain CMGv4 Products in Canada[1]

Table 1 Registered Cydia pomonella granulovirus strain CMGv4 Products in Canada[1]

Registration No.	Marketing Class	Registrant	Product Name	Formulation	Guarantee (Occlusion bodies per litre)
26532	Technical	BIOTEPP INC.	CYDIA POMONELLA GRANULOVIRUS	suspension	4×10^{13}
26533	Commercial	BIOTEPP INC.	VIROSOFT CP4	suspension	4×10^{13}

[1] As of 26 July 2018.

Appendix II Label Amendments for Products Containing *Cydia pomonella* granulovirus strain CMGv4

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following label statements are to be included on the technical grade active ingredient label (PCP Reg. No. 26532):

I) The following statement must be included under the **PRINCIPAL DISPLAY** panel:

"CAUTION – EYE AND SKIN IRRITANT"

II) Under **PRECAUTIONS:**

Remove

"Wear a long-sleeved shirt, long pants, waterproof gloves, shoes, socks and eye goggles when handling or mixing/loading the product and during all clean-up/repair activities"

Replace With

"Wear a long-sleeved shirt, long pants, water-proof gloves, shoes, socks, eye goggles and a NIOSH approved mist filtering mask or NIOSH approved mist filtering respirator when handling."

The following label statements are to be included on the end-use product label (PCP Reg. no. 26533):

I) The following statement must be included under the **PRINCIPAL DISPLAY** panel:

"CAUTION – EYE AND SKIN IRRITANT"

II) Under **RESTRICTED ENTRY INTERVAL** section, the following statements must be added **on all end-use product label**:

"DO NOT enter or allow re-entry into treated areas for 4 hours or until sprays have dried, unless wearing appropriate personal protective equipment including mist filtering NIOSH-approved respirator/mask, long-sleeved shirt, long pants, shoes plus socks, and waterproof gloves."

III) Under **PRECAUTIONS**, the following statements must be added **on end-use product label**:

Remove

"Wear a long-sleeved shirt, long pants, waterproof gloves, shoes, socks and eye goggles when handling or mixing/loading the product and during all clean-up/repair activities"

Replace With

"Wear a long-sleeved shirt, long pants, water-proof gloves, shoes, socks, eye goggles and a NIOSH approved mist filtering mask or NIOSH approved mist filtering respirator when handling, mixing/loading, or applying the product and during all clean-up/repair activities."

Add

"May irritate the skin and eyes. Avoid breathing spray mist."

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

"Can be applied up to and including the day of harvest. The pre-harvest interval (PHI) is 0 days."

IV) The following statements must be included in a section entitled **ENVIRONMENTAL PRECAUTIONS on end-use product label**:

"To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay."

"Avoid application when heavy rain is forecast."

"Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

V) The following statements must be included under the **DIRECTIONS FOR USE SECTION for end-use product:**

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."